

REMARKS

Claims 1-24 are pending in this application. Claims 3, 6, and 9 have been amended. Claims 2, 4, 5, 7, 8, and 15-17 have been canceled without prejudice or disclaimer to the subject matter described therein, and claims 1, 10-14, and 18-24 have been withdrawn, leaving claims 3, 6, and 9 remaining. Claims have been canceled in the expectation that the amendments will place this application in condition for allowance.

The amendments do not introduce new matter within the meaning of 35 U.S.C. §132. Basis for the claim amendments is found on page 4, line 17 to page 45, line 1; in claims 1-24 as originally filed; and elsewhere throughout the specification and claims. Accordingly, entry of the amendments is respectfully requested.

1. Objections to the Drawings

The Office Action objects to the drawings because the actual figure 10 has not been submitted by the Applicants.

Applicants have amended the Specification to remove reference to Figure 10. Accordingly, Applicants respectfully request the Examiner to reconsider and withdraw the objection to the drawings.

2. Objections to Sequence Compliance

The Office Action objects to Applicants compliance with the sequence requirements because applicants do not provide a SEQ ID NO for several sequences recited in the specification and claims, for example pages 6, 31, 39, 41 and figure descriptions for figures 3 and 6.

Applicants have amended the Specification and claims to insert "SEQ ID NO: ___" where appropriate, and have removed other non-essential sequences, such as primers, from the Specification. Accordingly, Applicants respectfully request the Examiner to reconsider and withdraw the objection to Applicants compliance with the sequence requirements.

3. Objections to the Claims

The Office Action objects to claim 2 because of the following informalities: Claim 2 does not recite the full biological name of the microorganism *A. ureafaciens* K2032.

Applicants have amended the claims to insert the full biological name of the referenced microorganisms. Accordingly, Applicants respectfully request the Examiner to reconsider and withdraw the objection to claim 2.

4. Rejection of Claims 2-5 under 35 U.S.C. §101

The Office Action rejects claims 2-5 under 35 U.S.C. §101 because the claimed invention is directed to non-statutory subject matter: claims 2-5 are drawn to "a novel levan fructotransferase" or "a novel levan fructotransferase gene" both of which read on the product of nature.

Applicants thank the Examiner for his comments, and have amended the claims as suggested by the Examiner. Accordingly, Applicants respectfully request the Examiner to reconsider and withdraw the rejection under 35 U.S.C. §101.

5. Rejection of Claims 2-5 and 8-9 under 35 U.S.C. § 112, second paragraph

The Office Action rejects claims 2-5 and 8-9 under 35 U.S.C. §112, second paragraph, for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention, for the following reasons:

1. Claims 2-5, 8-9 recite the phrase "novel levan fructotransferase" and "novel levan fructotransferase gene". This phrase constitutes an opinion by applicant on the merits of the claim and is therefore not considered proper.

2. Claim 2 recites the phrase "derived from A. ureafaciens". The metes and bounds of this phrase is not clear to the Examiner.

3. Claim 2 recites the phrase: selectively produce "difructose dianhydride IV". The metes and bounds of the above phrase is not clear to the Examiner.

4. Claims 3-5 recite the phrase "base sequence." It is not clear to the Examiner as to what applicants mean by the above phrase.

5. Claims 3-6 and 15 recite the term "gene" in order to claim cDNA. The use of the above term leads to ambiguity since it is well known in the art that large DNA sequences comprising the full complement of a gene such as the regulatory sequences and introns and exons and 5' and 3' untranslated regions are called "genes" and cDNAs are simply called "polynucleotides".

6. Claim 15 recites the phrase "bacterial species anchoring". The metes and bounds of the above phrase in the context of the above claim is not clear to the Examiner, specifically the term "anchoring".

7. Claim 16 recites the phrase "fructotransferase has histidine residues at its N- or C-terminus". It is not clear to the Examiner whether applicants are referring to the histidines that form the actual amino acid sequence of the enzyme or the external "6X HIS-tag" that is sometimes added to the N-or C-terminus in order to aid purification of the recombinant protein using an affinity column.

Applicants have canceled claims 2, 4, 5, 7, 8, and 1-17, and have amended claims 3, 6, and 9. Applicants have deleted the word "novel" from the amended claims, have replaced the term "derived from" with "isolated from", and have replaced the terms "gene" and "base sequence" with "polynucleotide", all as suggested by the Examiner.

Accordingly, Applicants respectfully request the Examiner to reconsider and withdraw the rejection under 35 U.S.C. §112, second paragraph.

**6. Rejection of Claims 7, 9, and 15-17 under 35 U.S.C. § 112,
first paragraph**

The Office Action rejects claims 7, 9, and 15-17 under 35 U.S.C. §112, first paragraph, for the following reasons:

1. Claims 7 and 9 are rejected as the invention appears to employ novel vector and bacterial strain. Since the vector and strain are essential to the claimed invention, they must be obtainable by a repeatable method set forth in the specification or otherwise be readily available to the public. The claimed plasmids' sequences are not fully disclosed, nor have all the sequences required for their construction been shown to be publicly known and freely available. The enablement requirements of 35 U.S.C. § 112 may be satisfied by a deposit of the plasmid/strain. The specification does not disclose a repeatable process to obtain the vectors and it is not apparent if the DNA sequences are readily available to the public. Accordingly, it is deemed that a deposit of these plasmids should have been made in accordance with 37 CFR 1.801-1.809.

2. Claims 15-17 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a process of making a levan fructotransferase enzyme consisting of SEQ ID NO: 1 using a host cell transformed with a expression vector comprising the polynucleotide with SEQ ED NO:2, does not reasonably provide enablement for making any levan fructotransferase of isolated from any or all sources using a host cell transformed with any polynucleotide isolated from any source and encoding a levan fructotransferase. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make the invention commensurate in scope with these claims.

3. Claims 15-17 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. These claims are directed to a method of preparing a genus of polypeptides using a genus of polynucleotides.

Applicants have canceled claims 2, 4, 5, 7, 8, and 1-17, and have amended claims 3, 6, and 9. Applicants respectfully traverse the remaining rejection, relating to the Examiner's suggestion that a deposit of these plasmids "should have been made in accordance with 37 CFR 1.801-1.809". Applicants' deposit of biological material has been made in compliance with the Budapest Treaty, as shown by the Certificate of Deposit appended to the Application as filed on page 46. The Korean Collection for Type Cultures is a recognized depository under the Budapest Treaty, and the Examiner lacks authority to question the official action of the United States Congress in ratifying the Budapest Treaty and recognizing the authority of that depository. The Receipt issued by that organization is *prima facie* evidence of full compliance with the Budapest Treaty. Lacking any reason of record for the Examiner to question the accuracy or legitimacy of the Receipt, this rejection must be withdrawn.

Accordingly, Applicants respectfully request the Examiner to reconsider and withdraw the rejection under 35 U.S.C. §112, first paragraph.

7. Rejection of Claim 2 under 35 U.S.C. §102(a)

The Office Action rejects claim 2 under 35 U.S.C. §102(a) as being anticipated by Song, et al. (SPTREMBL Accession No. Q9KJDO, 10-1-2000) and by Song, et al. (Enz. Microbial Technol., 2000, Vol.

27:212-218). As the basis for this rejection, the Office Action states:

This rejection is based upon the public availability of the amino acid sequence information in a public database prior to the date of application for patent in the United States. Claim 2 of the instant application is drawn to a levan fructotransferase isolated from *A. ureafaciens* having the amino acid sequence depicted in SEQ ID NO: 1, which is capable of hydrolyzing levan to produce difructose dianhydride IV. Song et al. disclose an amino acid sequence of a levan fructotransferase enzyme that is 100% identical to the amino acid sequence SEQ ID NO: 1.

Applicants respectfully traverse this rejection on the basis that the two cited references are not **prior** art, as required under §102(a). In particular, §102(a) provides as follows:

A person shall be entitled to a patent unless ... the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, **before the invention thereof** by the applicant for a patent [emphasis added.]

The effective filing date of the present application is the first foreign priority date: October 19, 1999, and the date of invention by Applicants was clearly no later than that date. The two cited references are both dated in 2000, and are not valid references under §102(a). Further, as the two Song, et al. references are Applicants' own work, Applicants clearly could not and did not publish their work before the invention thereof. Song, et al. (SPTREMBL Accession No. Q9KJDO, 10-1-2000) and Song, et al. (Enz. Microbial Technol., 2000, Vol. 27:212-218) do not anticipate the present claims.

Accordingly, Applicants respectfully request the Examiner to reconsider and withdraw this rejection.

8. Rejection of Claims 2 and 15 under 35 U.S.C. §102(b)

The Office Action rejects claims 2 and 15 under 35 U.S.C. §102(b) as being anticipated by Tanaka, et al. (J. Biochem., 1983, Vol. 94(5):1569-1578), Tanaka, et al. (J. Biochem., 1985, Vol. 97(6):1679-88), and Nippon Oil Company (NIOC) (GenSeq database accession No. AAY04105, 6-10-1999). As the basis for this rejection, the Office Action states:

Claim 2 is rejected under 35 U.S.C. 102(b) as being anticipated by Tanaka (a) et al. (J. Biochem., 1983, Vol. 94(5):1569-1578) and Tanaka (a) et al. (J. Biochem., 1985, Vol. 97(6):1679-88). This rejection is based upon the public availability of a printed publication more than one year prior to the date of application for patent in the United States. Claim 2 of the instant application is drawn to a levan fructotransferase isolated from *A. ureafaciens* having the amino acid sequence depicted in SEQ ID NO: 1, which is capable of hydrolyzing levan to produce difructose dianhydride IV. Tanaka (a) et al. or Tanaka (b) et al. discloses an identical enzyme, a levan fructotransferase isolated from *A. ureafaciens* which is capable of hydrolyzing levan to produce difructose dianhydride IV. Therefore, Tanaka et al. Anticipate claim 2 as written. The reference does not provide the amino acid sequence SEQ ID NO:1 as the sequence of the isolated enzyme. However, Examiner takes the position that amino acid characteristic is an inherent character of any enzyme. Furthermore, as the enzyme in the reference and the instant enzyme have identical source and activity, Examiner takes the position that the reference enzyme and the instant claimed enzyme are one and the same.

Claim 15 is rejected under 35 U.S.C. 102(b) as being anticipated by Nippon Oil Company (NIOC) (GenSeq database

accession No. AAY04105, 6-10-1999). This rejection is based upon the public availability of a printed publication more than one year prior to the date of application for patent in the United States. Claim 15 of the instant applica6orri-s_Jrawn to a method of preparation of levan fructotransferase by culturing a transformant, transformed with a expression vector comprising the polynucleotide encoding levan fructotransferase followed by harvesting and homogenizing cells and isolating the expressed enzyme. NIOC disclose an identical method of making the enzyme using transformed cells comprising a vector expressing a levan fructotransferase. Therefore NIOC anticipates claim 15 as written.

Applicants respectfully traverse this rejection on the basis that NIOC is not **prior** art, as required under §102(b). In particular, §102(b) provides as follows:

A person shall be entitled to a patent unless ... the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Further, 35 U.S.C. §365(c) provides as follows:

In accordance with the conditions and requirements of section 120 of this title, an international application designating the United States shall be entitled to the benefit of the filing date of a prior national application or a prior international application designating the United States, and a national application shall be entitled to the benefit of the filing date of a prior international application designating the United States. If any claim for the benefit of an earlier filing date is based on a prior international application which designated but did not originate in the United States, the Director may require the filing in the Patent and Trademark Office of a certified copy of such application together with a translation thereof into the English language, if it was filed in another language.

Thus, the effective filing date of the present application is the

first foreign priority date: October 19, 1999. The Nippon Oil Company (NIOC) (GenSeq database accession No. AAY04105, 6-10-1999) reference was **not** published more than one year prior to the date of application for patent herein, is not a valid reference under §102(b), and does not anticipate the present claims.

Further, Applicants respectfully traverse this rejection on the basis that the Tanaka, et al. (J. Biochem., 1983, Vol. 94(5):1569-1578) and Tanaka, et al. (J. Biochem., 1985, Vol. 97(6):1679-88) references fail to teach the claimed subject matter. To constitute anticipation under 35 U.S.C. §102, **all** material elements of a claim must be formed in one prior art source. In re Marshall, 577 F.2d 301, 198 USPQ 344 (CCPA 1978); In re Kalm, 378 F.2d 959, 154 USPQ 10 (CCPA 1967). The Tanaka references do not disclose either a nucleotide or amino acid sequence, and thus is not tantamount to a disclosure of "one and the same" enzyme as suggested by the Examiner. Applicants respectfully decline to accept the Examiner's speculation in this regard particularly in view of the complete lack of any evidence to support the Examiner's position. Applicants note that the Examiner has utterly failed to discuss anything about the Tanaka references, other than a single, unsupported, conclusionary statement, which would appear to an acknowledgment that there is nothing in the documents to support the Examiner's position. It is well known in the art that more than one enzyme in a particular organism may have similar or

identical functional activity. Thus, in the absence of any evidence in the record that the enzymes described by Tanaka, et al. are the same as the claimed subject matter, the Examiner has failed to present a *prima facie* case of anticipation, and the Tanaka, et al. references do not anticipate the present claims.

9. Rejection of Claims 16-17 under 35 U.S.C. §103(a)

The Office Action rejects claims 16-17 under 35 U.S.C. §103(a) as being unpatentable over NIOC (GenBank Accession No. AAY04105 6-10-1999) as applied to claim 15 above, and further in view of the common knowledge in the art of molecular biology regarding the purification of recombinant proteins using Ni-ion affinity chromatography such as that generally taught in laboratory manuals such as Sambrook et al. (Molecular Cloning, A Laboratory Manual, 2nd Ed, Cold Spring Harbor Laboratory Press, 1989, pages 7.37-7.52). As the basis for this rejection, the Office Action refers to the reasons stated in the §102(b) rejection and states:

It is common knowledge in the art that adding nucleotides encoding 6-8 Histidine amino acids at either of the recombinant protein encoding sequences in an expression vector followed by expressing such recombinant protein in a host cells leads to formation of His-tagged protein: It is also common knowledge that tagged proteins can be easily purified by one single passage through a metal-ion column such as Ni column which adsorbs the His-tagged proteins which can be later eluted out as a homogenous protein by cleaving off the tag. Such teachings are found in common laboratory manuals such as that of Sambrook et al.

With the teaching of NIOC in hand, it would have been obvious to one of ordinary skill in the art to use the common knowledge available in the art to make His-tagged levan fructotransferase and isolate it in a pure form using the metal ion affinity chromatography. One of ordinary skill in the art would be motivated to do so in order to quickly purify the recombinant protein. One of ordinary skill in the art would have a reasonable expectation of success since NIOC provide the recombinant levan fructotransferase and the art provides additional method to tag and purify the recombinant protein.

Applicants have canceled claims 16-17. Accordingly, Applicants respectfully request that the Examiner reconsider and withdraw this rejection.

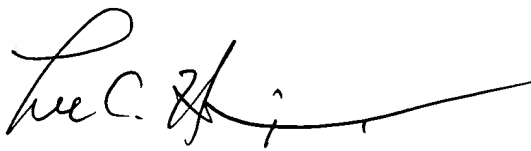
CONCLUSION

Based upon the above remarks, the presently claimed subject matter is believed to be clearly and distinctly claimed, fully enabled, novel, and patentably distinguishable over the prior art of record. The Examiner is therefore respectfully requested to reconsider and withdraw the rejections of remaining claims 3, 6, and 9, and allow all pending claims presented herein for reconsideration. Favorable action with an early allowance of the claims pending in this application is earnestly solicited.

The Examiner is welcomed to telephone the undersigned attorney if she/he has any questions or comments.

Respectfully submitted,

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